

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO.,)
LTD.,)
)
 Plaintiff,) C.A. No. 21-1015-JLH
)
v.)
)
SAREPTA THERAPEUTICS,)
INC.,)
)
 Defendant.)

Thursday, April 18, 2024
11:00 a.m.
Teleconference

844 King Street
Wilmington, Delaware

BEFORE: THE HONORABLE JENNIFER L. HALL
United States District Court Judge

APPEARANCES:

MORGAN LEWIS & BOCKIUS, LLP
BY: AMY M. DUDASH, ESQ.
BY: AMANDA S. WILLIAMSON, ESQ.
BY: WAN-SHON LO, ESQ.
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15 Counsel for the Defendant

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11:04:07 15
11:04:07 16 THE COURT: Good morning, everyone. This is Jen
11:04:10 17 Hall. We're here on the line for a status teleconference.
11:04:15 18 This is Nippon Shinyaku versus Sarepta. It's civil action
11:04:18 19 number 21-1015. We have a court reporter on the line today.
11:04:23 20 Can I have an appearance, please, for the plaintiffs?

11:04:25 21 MS. DUDASH: Good morning, Your Honor. This is
11:04:28 22 Amy Dudash from Morgan Lewis on behalf of Nippon Shinyaku
11:04:34 23 and MS Pharma and with me on the line are my colleagues from
11:04:39 24 Morgan Lewis, Amanda Williamson, Wan-Shon Lo, Krista Venegas
11:04:45 25 and Michael Sikora.

11:04:48 1 THE COURT: Good morning to all of you. And
11:04:50 2 let's of appearances for the defendant.

11:04:52 3 MR. BLUMENFELD: Good morning, Your Honor. It's
11:04:54 4 Jack Blumenfeld from Morris Nichols. Also on the line are
11:04:57 5 my partner, Megan Dellinger and from Latham & Watkins,
11:05:02 6 Michael Morin, Amanda Reeves, David Frazier and from the
11:05:06 7 Finnegan firm, William Raich and Ryan O'Quinn.

11:05:11 8 THE COURT: Good morning to all of you.

11:05:13 9 So I appreciate everybody getting on the phone
11:05:16 10 ON short notice. I think you can see that we've been
11:05:22 11 working through the pending motions. We're trying to figure
11:05:27 12 out how best to work through the pending motions after we
11:05:31 13 were recently reassigned this case and we recognized that
11:05:34 14 it's going to trial. So we're trying as best we can to
11:05:37 15 efficiently get everything ready so that we can put the case
11:05:42 16 to the jury.

11:05:43 17 We appreciated the letters that we got from the
11:05:46 18 parties this week. That was very helpful to us in
11:05:50 19 understanding what's left that needs to be decided before we
11:05:53 20 can get the case to trial and so we're trying to figure out
11:05:58 21 how best to prioritize our resources. And as you have all
11:06:04 22 figured out, some of that depends on what is actually going
11:06:07 23 to get tried in the upcoming trial.

11:06:08 24 So we wanted to ask some questions today about
11:06:11 25 the parties' proposal on some of the inequitable conduct

11:06:17 1 allegations. We didn't want to surprise anyone, so we put
11:06:20 2 on the docket what we were thinking, but we're happy to hear
11:06:25 3 any other suggestions or positions the parties have about
11:06:28 4 that.

11:06:28 5 So let's turn it over to plaintiff first, if you
11:06:31 6 want to start with the Court's questions and if you have
11:06:33 7 anything else you want to add, that's fine too.

11:06:36 8 MS. LO: Thank you, Your Honor. This is Shon Lo
11:06:40 9 behalf of Nippon Shinyaku.

11:06:41 10 In response to your first question whether a
11:06:42 11 jury finding that if NS failed to prove invalidity of the
11:06:50 12 Sarepta UWA patents, will that be dispositive of our
11:06:53 13 inequitable conduct and antitrust claims, and the answer is
11:06:56 14 no. Nippon Shinyaku's inequitable conduct theory is based
11:06:58 15 on affirmative, egregious misconduct by the inventors who
11:07:04 16 included fake data in the specification concerning the full
11:07:05 17 disclosed species from the claimed genus. And if such not
11:07:10 18 affirmative, egregious misconduct, we would still contend
11:07:13 19 that its false in material patentability. So you can see
11:07:15 20 that the enforceability of the patent does not rise and fall
11:07:20 21 with whether or not they survive an invalidity attack under
11:07:26 22 112.

11:07:28 23 And so therefore because, you know,
11:07:33 24 dispositive --

11:07:37 25 THE COURT: I didn't mean to interrupt. Go

11:07:39 1 ahead.

11:07:40 2 MS. LO: I apologize. And so I think that that
11:07:42 3 really weighs against, respectfully, bifurcating the
11:07:46 4 antitrust claims from trial. I think that none of the
11:07:51 5 authority that Sarepta cited in their briefing stands for
11:08:00 6 the proposition that an antitrust claim that is trial ready
11:08:03 7 should be bifurcated particularly when it doesn't promote
11:08:07 8 any sort of judicial efficiency or economy.

11:08:11 9 THE COURT: All right. Just sticking with that,
11:08:16 10 assuming I agree with you that maybe there's some economy in
11:08:23 11 having the jury hear about the practice before the patent
11:08:29 12 office and there might be some factual overlap with some of
11:08:32 13 the validity issues and relevant testimony that would apply
11:08:37 14 to both the patent claims and the antitrust claims, what
11:08:47 15 about maybe putting to the jury the inequitable conduct
11:08:52 16 elements of your Walker Process claim, but bifurcating out
11:08:57 17 the other elements of the antitrust claim, like relevant
11:09:01 18 market and antitrust injury? I mean, isn't that really too
11:09:05 19 complicated, to have the jury digest that stuff in addition
11:09:08 20 to the patent stuff?

11:09:09 21 MS. LO: Well, I think, in our view this is one
11:09:13 22 of those rare cases where the antitrust claims are actually
11:09:16 23 fairly straightforward. The relevant market, these are FDA
11:09:19 24 approved drugs, they're direct competitors, it's a
11:09:24 25 two-player market. So in terms of those kinds of findings,

11:09:26 1 I don't think that -- you know, the jury would hear the same
11:09:30 2 evidence from Nippon Shinyaku's fact witnesses and expert
11:09:31 3 witnesses about the products, the market, the FDA indication
11:09:37 4 and how, you know, drugs get approval, we actually think
11:09:47 5 that, you know, there would be efficiencies in trying the
11:09:52 6 antitrust claim and the fact -- to ask the same jury to
11:09:58 7 decide on both factors in the same trial.

11:10:01 8 THE COURT: And that's something that you feel
11:10:04 9 you can get done if the Court only gives each side 11 hours
11:10:09 10 to try their entire case?

11:10:10 11 MS. LO: If that's the case, I'm sure the answer
11:10:13 12 is yes, we would get it done.

11:10:17 13 THE COURT: Okay. And do you have a position on
11:10:20 14 question no. 2 of the Court's order?

11:10:25 15 MS. LO: I think this is a closer question. I
11:10:30 16 think there is a reasonable argument that a jury finding
11:10:37 17 that Sarepta failed to prove invalidity under 103, if
18 Sarepta failed to prove that Nippon Shinyaku's patents are
11:10:42 19 obvious, that this could be dispositive of their inequitable
11:10:46 20 conduct claims and that's based on the nature of their
11:10:48 21 theory, which is based on a failure to disclose a reference
11:10:52 22 that they are relying on for their obviousness -- for their
11:10:57 23 obviousness counterclaim, as well as some data relating to
11:11:03 24 unexpected results, an argument that was presented to the
11:11:06 25 patent office that we are not relying on to be but

11:11:14 1 obviousness.

11:11:14 2 THE COURT: Okay. And it looks like maybe the
11:11:17 3 Court had a -- and I want to make sure. And I apologize,
11:11:22 4 I'm trying to get up to speed as fast as possible. So
11:11:25 5 Sarepta -- okay. Understood.

11:11:29 6 Okay. And then we were just confused about your
11:11:36 7 suggestion in your letter that the jury might be giving an
11:11:42 8 advisory verdict on the inequitable conduct allegation and
11:11:45 9 wanted to make sure exactly what we meant by that. Are you
11:11:49 10 amenable to having the Court determine the inequitable
11:11:54 11 conduct and would that be dispositive of the antitrust
11:11:57 12 claim?

11:11:57 13 MS. LO: Your Honor, it's our understanding that
11:12:00 14 the inequitable conduct is properly decided by the Court;
11:12:03 15 but however, we thought that a jury advisory verdict to a
11:12:08 16 jury whose heard all of the evidence might be helpful to the
11:12:11 17 Court. We are amenable to having you decide our inequitable
11:12:15 18 conduct claim and we do concede that a finding of no
11:12:19 19 inequitable conduct by you would be dispositive of our
11:12:23 20 Walker Process fraud claim.

11:12:26 21 THE COURT: Okay. So I just wanted to make
11:12:30 22 certain we're very clear on the record here. You would not
11:12:34 23 object to the Court's deciding your inequitable conduct
11:12:38 24 claim. And if the Court, meaning the judge, finds against
11:12:43 25 you on that, that that would result in a judgment for

11:12:49 1 Sarepta on your Walker Process claim as well. You agree
11:12:52 2 that that is okay, that's something that you are okay with?

11:12:56 3 MS. LO: Yes, we agree. I think that that is
11:12:59 4 based on the case law, the guiding case law.

11:13:03 5 If I can circle back in terms of timing of the
11:13:07 6 case, you know, 11 hours each side I think is a little
11:13:11 7 tight. You know, I think we originally asked for seven days
11:13:15 8 of trial in anticipation of kind of, you know, cross-patent
11:13:19 9 claims and stuff, but I think that would still be our
11:13:23 10 request if the Court would grant us that leeway.

11:13:27 11 THE COURT: Okay. Well, what I'm thinking now
11:13:30 12 is, based on your agreement that the Court could decide the
11:13:36 13 inequitable conduct portion of the case, which, again, your
11:13:41 14 Walker Process claim is based on the same conduct as your
11:13:45 15 inequitable conduct claim, right?

11:13:47 16 MS. LO: That's correct. Well -- yeah.

11:13:49 17 THE COURT: And so based your agreement that the
11:13:51 18 Court could decide the inequitable conduct element -- you're
11:13:57 19 basically saying the Court can decide the inequitable
20 conduct element of your Walker Process claim. I mean,
11:14:03 21 that's what that amounts to, right?

11:14:05 22 MS. LO: Correct. And then the jury would need
11:14:07 23 to decide the antitrust aspect of the claims.

11:14:10 24 THE COURT: Which include the relevant market
11:14:12 25 and antitrust injury. Anything else?

11:14:15 1 MS. LO: The specific intent to monopolize the
11:14:18 2 dangerous probability of success and damages.

11:14:22 3 THE COURT: Okay. Understood. But none of the
11:14:25 4 stuff that has to do with the practice before the patent
11:14:28 5 office?

11:14:28 6 MS. LO: That's right.

11:14:30 7 THE COURT: Okay. I guess what I'm wondering
11:14:33 8 is, maybe the best thing to do, so that we can get the jury
11:14:38 9 in and out of here, is to let the parties try their case to
11:14:43 10 the jury in the 11 hours they're given. And then maybe the
11:14:47 11 parties, in the evening, after the jury is released, do a
11:14:54 12 couple more hours at the end of the day for the inequitable
11:14:57 13 conduct claims. So that's one thing I'm thinking about.

11:15:06 14 Any comments on that?

11:15:08 15 MS. LO: I think we would be amenable to that.
11:15:10 16 We really appreciate the Court's suggestion to set aside
11:15:16 17 time in the evening for that. Just, I think that we would
11:15:19 18 be able to present our inequitable conduct portion in a few
11:15:27 19 hours. It would not take a substantial amount of time, at
11:15:32 20 least, you know, from our perspective presenting our
11:15:37 21 affirmative case.

11:15:38 22 THE COURT: Okay. All right. Let me turn it
11:15:39 23 over to the other side and why don't you let me know if you
11:15:43 24 have any comments on anything I've said so far or anything
11:15:47 25 the other side has agreed to so far.

11:15:50 1 MR. MORIN: Your Honor, this is Mike Morin from
11:15:53 2 Latham & Watkins for Sarepta. I guess I'll kick things off
11:15:56 3 from here. Good morning, Your Honor.

11:15:59 4 In view of the plaintiffs' position with respect
11:16:03 5 to the Court deciding unenforceability, that just further
11:16:08 6 solidifies what we think is the best approach here, that the
11:16:11 7 up coming trial be focused on purely the patent issues at
11:16:16 8 the trial, the validity, infringement and damages issues for
11:16:21 9 the patent case.

11:16:22 10 We believe that on questions 1 and 2, that if
11:16:24 11 the validity verdict of the jury doesn't dispose of the
11:16:28 12 unenforceability and antitrust issues, at the very least
11:16:32 13 will very significantly narrow them. It could dispose of
11:16:35 14 them. One of the primary positions that the other side has
11:16:40 15 is that the inventor signed an oath claiming to have
11:16:46 16 invented more than he invented. But if the jury rejects the
11:16:49 17 arguments that the claims aren't supported by the written
11:16:50 18 description and they reject the enablement argument, that's
11:16:54 19 going to go a long way towards either disposing of or
11:16:57 20 significantly narrowing the case.

11:16:59 21 We think an upcoming trial that is limited to
11:17:01 22 the issues -- as our friends on the other side say, we have
11:17:05 23 competing patents, there's already a lot to do and we go
11:17:08 24 ahead and try those competing patent issues and then we'll
11:17:12 25 have a much narrower set of issues. If we have to come back

11:17:17 1 and do a bench trial on unenforceability or have to make
11:17:20 2 submissions on unenforceability, it will be greatly narrowed
11:17:20 3 if not eliminated at that time. So we think that the
11:17:24 4 decisions on validity are going to go a long way towards
11:17:28 5 resolving them and it may be that we never have to come back
11:17:31 6 and revisit unenforceability or antitrust at that point in
11:17:37 7 time in any event.

11:17:38 8 So that's what we would propose for the upcoming
11:17:44 9 trial. And I don't think, in a compressed schedule, having
11:17:49 10 extra hours on inequitable conduct outside the presence of
11:17:55 11 the jury is the best way to kind of focus and use that time.
11:18:00 12 I think we should try to get in and resolve the primary
11:18:03 13 issues in the case on the patent issues. And like I said, I
11:18:04 14 think that's likely to be dispositive at the end of the day
11:18:06 15 or at least greatly narrow the issues, either such that
11:18:10 16 there doesn't have to be a trial from a legal perspective or
11:18:13 17 that the parties want the main issues to be resolved may be
11:18:14 18 able to resolve their differences at that time.

11:18:19 19 In any event, the other advantage it has for the
11:18:19 20 Court, Your Honor, is that as identified in our letter,
11:18:22 21 about half of the summary judgment and Daubert motions could
11:18:26 22 then be postponed and you may never have to address them at
11:18:30 23 all if we go ahead and kind of bifurcate the
11:18:33 24 unenforceability issues as well.

11:18:36 25 THE COURT: Well, let me ask you this. I mean,

11:18:38 1 some of the summary judgment motions have to do with
11:18:43 2 inequitable conduct and normally we wouldn't hear or
11:18:49 3 entertain summary judgment motions if we were going to
11:18:51 4 proceed to a bench trial anyway. I guess I'm wondering, it
11:18:56 5 could be postponed in the sense we could bring it up again
11:19:00 6 in the post-trial briefing.

11:19:03 7 Is your main objection -- well, I take it that
11:19:06 8 you have an objection to doing a couple hours of bench trial
11:19:10 9 after the jury is released each day. How long do you think
11:19:14 10 it will take you to try the inequitable conduct claims.

11:19:19 11 MR. MORIN: I think they're kind of scattershot
11:19:22 12 issues. I think we could probably do them in extra time at
11:19:26 13 the end of the day. It's not so much I have an objection in
11:19:30 14 the sense I think it's legally wrong, I just don't think
11:19:33 15 it's the best use of the Court's or the parties' time. What
11:19:36 16 I'm representing to the Court is I believe that the
11:19:38 17 disposition of the patent issues is likely to greatly
11:19:41 18 narrow, if not eliminate, the unenforceability issues. And
11:19:44 19 if there's still things that remain, we can take them up at
11:19:48 20 a later time. Our friends on the other side are agreeing
11:19:51 21 that the Court can decide unenforceability, so that's a
11:19:54 22 threshold and necessary prerequisite for an antitrust claim
11:19:59 23 so that we could, if necessary, come back and do a day later
11:20:03 24 on in time of a bench trial on those separate issues. But
11:20:07 25 what I'm proposing to the Court is that may not end up

11:20:10 1 ultimately being necessary in any event, but that would
11:20:13 2 strike us a more efficient and appropriate way to proceed.
11:20:17 3 So it's not that I'm objecting and saying you don't have
11:20:20 4 discretion to bring in witnesses after the jury leaves each
11:20:25 5 day, but I think on a competing patent case and having just
11:20:26 6 come out of this jury trial up in Delaware with Judge
11:20:29 7 Jordan, we know how busy we are at the beginning and the end
11:20:33 8 of the day every day when we have multiple patents going
11:20:36 9 both directions, adding to it an issue that may never end up
11:20:40 10 needing to be decided in additional witnesses at the end of
11:20:43 11 the day is just not what I believe to be the best use of the
11:20:46 12 very busy Court and the parties' resources. It may be we
11:20:50 13 have to address it and if we do, we can address it in a day
11:20:54 14 later on.

11:20:54 15 THE COURT: You mentioned that the other side
11:20:56 16 had agreed that the Court could decide the inequitable
11:20:59 17 conduct issue, which includes the inequitable conduct
11:21:03 18 element of the Walker Process claim. If I decide that
11:21:10 19 they've shown inequitable conduct, are we -- do you agree
11:21:16 20 that that's dispositive of those elements of their Walker
11:21:19 21 Process claim? Or I think you understand what I'm asking
11:21:25 22 here.

11:21:25 23 MR. MORIN: For the record, if the Court were to
11:21:28 24 find that we committed inequitable conduct, then that
11:21:34 25 finding would be binding on us. Now, as the Court is aware

11:21:38 1 for up front enforceability, Walker Process requires even
11:21:41 2 more egregious and even more improper conduct. So it
11:21:45 3 wouldn't necessarily fully resolve -- if you rule against
11:21:50 4 them, the antitrust case is over, as I think our friends
11:21:53 5 have agreed. If you rule against us, there's still maybe
11:21:56 6 some more work to be done. And in addition, of course you
11:22:00 7 have all the market issues and all of the damages issues.
11:22:03 8 But as Your Honor is aware, I think we've had issues in
11:22:05 9 front of Your Honor before this, the egregiousness of
11:22:07 10 conduct that's required to satisfy a Walker Process claim is
11:22:13 11 even higher under the law than a pure unenforceability
11:22:16 12 claim. So it will resolve it definitively if they lose. If
11:22:21 13 they were to win, which, again, for the record we don't
11:22:24 14 think they will, then there will be some more work to be
11:22:28 15 done.

11:22:28 16 THE COURT: But if the Court makes a specific
11:22:30 17 finding about -- and I'm not saying that I will, I'm just
11:22:34 18 trying to make sure we're all clear about how we're going to
11:22:37 19 proceed. If the Court makes a specific finding that a
11:22:41 20 reference was material and there was intent to deceive, that
11:22:45 21 would be something that you would be estopped from
11:22:47 22 relitigating.

11:22:48 23 MR. MORIN: Yes. Yes, Your Honor. We agree
11:22:51 24 with that.

11:22:51 25 THE COURT: Okay.

11:22:52 1 MR. MORIN: The Court's finding on those issues
11:22:56 2 would control.

11:22:57 3 THE COURT: Okay.

11:22:59 4 MS. LO: Your Honor, may I respond?

11:23:00 5 THE COURT: Yes.

11:23:01 6 MS. LO: So in terms of counsel's -- so, first
11:23:05 7 of all, there's no precedent for bifurcating -- inequitable
11:23:13 8 conduct is a patent-related claim and none of the precedent
11:23:16 9 cited by Sarepta's counsel stands for the proposition that,
11:23:20 10 you know, the inequitable conduct aspect in an antitrust
11:23:24 11 claim should also be bifurcated and tried with the antitrust
11:23:27 12 claims. And I think there's good reason for that, because
11:23:30 13 that would lead to even more duplication and prejudice.

11:23:33 14 So, for example, if we were going to bifurcate
11:23:37 15 consideration of the antitrust of the inequitable conduct
11:23:41 16 issues, there would be witnesses traveling internationally,
11:23:45 17 witnesses might not be available to come. For example, the
11:23:48 18 inventors on the Sarepta patents reside in Australia and the
11:23:53 19 special master determined that Sarepta has no ability to
11:23:57 20 compel them to appear for trial in Delaware or for
11:24:00 21 deposition. And so therefore, you know, Nippon Shinyaku
11:24:05 22 might be severely prejudiced. We may not have access to the
11:24:09 23 witnesses we would need for inequitable conduct. And on the
11:24:12 24 flip side, Nippon Shinyaku is also bringing in witnesses
11:24:15 25 from Japan to testify at trial already and we would have to

11:24:18 1 bring those witnesses back, assuming that they're available,
11:24:22 2 for a subsequent bench trial.

11:24:24 3 Second of all, I strongly disagree with my
11:24:28 4 friend's characterization of our inequitable conduct claim.
11:24:32 5 Again, this is about the -- a data point that supports the
11:24:41 6 written description of the claims that was included in the
11:24:44 7 specification. The inventor said that they tested this
11:24:49 8 compound and observed activity at a certain concentration
11:24:52 9 when, in fact, they did not have that data. They never
11:24:55 10 tested that data at the concentration as represented, but
11:24:59 11 the patent says what it says. So if the jury finds that
11:25:02 12 yes, written description is satisfied because of this entry
11:25:06 13 in -- because of this passage in the specification, that has
11:25:09 14 nothing to do with whether or not that passage in the
11:25:12 15 specification was false or submitted with the intent to
11:25:18 16 mislead the patent office or whether or not, you know, the
11:25:21 17 patent office would have rejected the claims absent that
11:25:26 18 support in the specification. Again, you can see kind of
11:25:29 19 there, right there how the 112 issues and the
11:25:32 20 unenforceability issues, at least with respect to the
11:25:37 21 patents, are really intertwined. Again, arguing against
11:25:40 22 bifurcation of those issues.

11:25:43 23 MR. MORIN: Your Honor -- I thought you were
11:25:45 24 done, I'm sorry.

11:25:47 25 THE COURT: Please.

11:25:48 1 MS. LO: And also I wanted to say there's also
11:25:50 2 an additional aspect of prejudice, potential prejudice on
11:25:54 3 Nippon Shinyaku which is the inevitable delay that
11:25:57 4 bifurcation would cause and that's a real recognized
11:26:01 5 prejudice. And for example, you know, Nippon Shinyaku would
11:26:05 6 need to wait to appeal on patent issues until the antitrust
11:26:09 7 claim is decided in the normal course and we don't know how
11:26:13 8 long that would take. Again, you know, to the extent that
11:26:16 9 Sarepta's counsel is suggesting that we should just set the
11:26:20 10 inequitable conduct issues aside for later, we don't think
11:26:23 11 that that makes any sense at all.

11:26:26 12 MR. MORIN: Your Honor, if I may respond
11:26:29 13 briefly?

11:26:30 14 THE COURT: Go ahead.

11:26:31 15 MR. MORIN: Just taking the points in turn.
11:26:37 16 Opposing counsel first said that they're not aware of any
11:26:40 17 precedent for bifurcating unenforceability. I'm not a
11:26:48 18 Delaware lawyer, but I've been practicing there 25 years.
11:26:50 19 I'm not sure -- in almost every case, unenforceability, when
11:26:55 20 the parties have agreed it's decided by the Court, its been
11:26:58 21 taken up at a subsequent and separate hearing, if necessary.
11:27:01 22 Certainly wouldn't be unusual to do so and everyone agrees
11:27:05 23 that that could be dispositive if they lose on
11:27:07 24 unenforceability with the rest of the issues in the case.
11:27:11 25 We're not even saying anyone would have to wait for the

11:27:13 1 appeal to come back for unenforceability. If the patents
11:27:17 2 are found invalid or either way, we could schedule a bench
11:27:21 3 trial down the road, if necessary -- again, I'm not sure
11:27:24 4 it's going to be necessary, I think it's likely not -- at
11:27:27 5 some point in time in the summer or the fall, whatever time
11:27:30 6 it might be, we, Sarepta, will make our witnesses available
11:27:34 7 as I suspect NS will make its witnesses available, if
11:27:37 8 necessary. But we think in the ordinary course where the
11:27:39 9 parties agree that the Court will decide unenforceability,
11:27:43 10 that the best way to go about it is to have a separate short
11:27:47 11 bench proceeding, if necessary. And again, I think,
11:27:50 12 depending on the results of the first trial, it may not be
11:27:53 13 necessary. So that's what we would propose doing there,
11:27:57 14 Your Honor.

11:27:57 15 THE COURT: Okay. All right. Well, we'll put
11:28:00 16 an oral order up on the docket, hopefully later today, but I
11:28:05 17 can tell you that my inclination is that we'll go to trial
11:28:10 18 on the patent issues and we'll do a separate bench trial to
11:28:18 19 occur in the evenings after the jury is released to resolve
11:28:22 20 all of the inequitable conduct issues, including the
11:28:26 21 inequitable conduct elements over the Walk Process claim.
11:28:32 22 I'm disinclined to put the issues of relevant market and
11:28:36 23 antitrust injury and intent to monopolize to the jury in
11:28:40 24 this trial, mostly because I agree with Sarepta that it's
11:28:45 25 going to be hard enough for the jury to digest the patent

11:28:51 1 concepts when we've got the parties asserting patents
11:28:55 2 against each other. But we'll make a final decision on that
11:28:58 3 and put that up in an oral order.

11:29:01 4 As you might have guessed, I'm inclined to give
11:29:04 5 the parties 11 hours in total. We can decide this finally
11:29:10 6 at the pretrial conference, but I think that will encompass
11:29:14 7 time for opening statements, witness testimony and closing
11:29:18 8 arguments, because I'd like to be able to get the case to
11:29:22 9 the jury by Friday morning the week of trial.

11:29:28 10 And the parties should talk about how long they
11:29:30 11 think it's going to take them to put on their witnesses in
11:29:34 12 the evening so that we have an understanding about what our
11:29:38 13 schedule is going to look like the trial week for hearing
11:29:42 14 the inequitable conduct evidence.

11:29:48 15 The other thing I had was, I want to make sure I
11:29:52 16 fully understand what's going on here with respect to the
11:29:55 17 parties' infringement cases against each other. So I'm
11:30:01 18 looking at the letter that I got. I have NS asking for
11:30:12 19 summary judgment of infringement, but I also saw a
11:30:17 20 stipulation on the docket that said that Sarepta dropped
11:30:23 21 their non-infringement defense. Can somebody fill me in as
11:30:28 22 to what's going on here?

11:30:29 23 MS. LO: Yes, Your Honor. This is Shon Lo for
11:30:33 24 Nippon Shinyaku. So Sarepta stipulated that it wouldn't
11:30:36 25 raise any non-infringement defense, but has refused to

11:30:40 1 stipulate to actual infringement. And that was the genesis
11:30:43 2 behind our MSJ motion on infringement.

11:30:50 3 THE COURT: Okay.

11:30:51 4 MS. LO: And in terms of --

11:30:52 5 THE COURT: And I'll admit, I haven't read it
11:30:55 6 all yet. We're just working through the big stack of papers
11:30:58 7 that we have. But are they opposing entry of judgment of
11:31:06 8 infringement?

11:31:06 9 MR. MORIN: This is Mike Morin, Your Honor. I'm
11:31:09 10 sorry if there's been a miscommunication. We stipulate to
11:31:13 11 infringement under the Court's claim construction, so you
11:31:16 12 don't have to resolve the summary judgment of infringement
11:31:19 13 against us. We will stipulate to infringement under the
11:31:22 14 Court's claim construction. Our sole defense other than
11:31:25 15 unenforceability will be on obviousness at the trial.

11:31:28 16 THE COURT: Okay. Got it. And on that note, I
11:31:31 17 did notice, as I was talking here, that my oral order from
11:31:35 18 yesterday had a typo in it. It referred to 112, but of
11:31:39 19 course you're asserting a 103 defense. Hopefully everybody
11:31:44 20 understood what I was asking.

11:31:45 21 MR. MORIN: We did, Your Honor.

11:31:49 22 THE COURT: Great. Did anybody else have
11:31:51 23 anything they wanted to raise as long as we're all here on
11:31:54 24 the phone today?

11:31:55 25 MR. MORIN: I have a couple things, with Your

11:31:57 1 Honor's indulgence, since we're all together on this.

11:32:00 2 The first one is, as we just indicated, we've
11:32:02 3 stipulated to infringement and are only running obviousness.
11:32:06 4 We've agreed to limit ourselves, especially given the time
11:32:09 5 to trial and the jury's going to be hearing patents both
11:32:12 6 ways to no more than two representative patent claims. The
11:32:15 7 other side is still insisting that it wants six claims.
11:32:19 8 We're not sure why that's necessary especially given our
11:32:22 9 stipulation to infringement. We'd ask the Court to
11:32:25 10 encourage them to get to one or two representative claims,
11:32:28 11 pick their most valid claims and that should do it and
11:32:32 12 simplify issues for the Court and the jury. That's the
11:32:35 13 first issue.

11:32:36 14 I have a couple others that I'd like to bring
11:32:38 15 up, but I'll pause there.

11:32:40 16 THE COURT: That's fine. Let me ask plaintiff,
11:32:42 17 are you planning to try all six or are you planning, at some
11:32:45 18 on point in time, to reduce it?

11:32:47 19 MS. LO: Your Honor, my understanding is that we
11:32:50 20 would like to try all six, but we could reduce it by one
11:32:54 21 claim, I suppose. So the NS patents are related and similar
11:32:58 22 in subject matter, but the claims are different types and
11:33:01 23 they have different elements and so, you know, there's
11:33:06 24 different obviousness issues at play. And we had more
11:33:10 25 asserted patents to begin with. We think five or six

11:33:15 1 asserted claims from the NS side is a reasonable amount to
11:33:17 2 try, particularly given the related underlying subject
11:33:20 3 matter.

11:33:21 4 THE COURT: Well, here's what I'll say about
11:33:23 5 that. You need to let the other side know no later than the
11:33:28 6 pretrial conference as to what claims you intend to try.
11:33:33 7 Whatever claims you tell them at the pretrial conference
11:33:38 8 that you want to assert, those are the ones that will be put
11:33:42 9 to the jury. And if you don't put on evidence about one of
11:33:45 10 them, then I will tell the jury at the end of the case that
11:33:48 11 we've granted judgment on the one you haven't put on any
11:33:51 12 evidence about. I think you know what I'm saying, which is
11:33:54 13 that if you're going to reduce and not try them all, you
11:33:57 14 need to do that by the pretrial conference.

11:34:00 15 MS. LO: Understood. Thank you, Your Honor. I
11:34:02 16 have a couple items to raise, if you'll indulge.

11:34:05 17 THE COURT: I think we've got a couple more
11:34:07 18 issues from the other side and then we'll turn it over.

11:34:10 19 MR. MORIN: Yes, Your Honor. The other one
11:34:12 20 that I'm not expecting Your Honor to try to resolve it here
11:34:16 21 today. But Your Honor probably noticed in the stack of
11:34:19 22 materials, we have a summary judgment of infringement
11:34:22 23 motion -- a motion for summary judgment of infringement on
11:34:26 24 our patents, being the Sarepta patents, against NS. And if
11:34:31 25 you look at the list of issues that they plan to raise as

defenses, they say non-infringement. Obviously we'd very much like the Court's help with the infringement summary judgment, because it follows directly from Judge Williams' claim construction and we think it's straightforward.

But also, an issue that they did not raise at claim construction has come up that they're now making kind of an 11th hour indefiniteness argument which we think is, A, for the Court to decide; B, wholly inconsistent with Judge Williams' claim construction; and C, basically waived because they didn't make it at the claim construction stage. And we'd like some guidance or at least some help dealing with that so that we're not trying to prepare for kind of a rogue defense getting ready for trial and know what the issues actually to be tried are. So we could use Your Honor's assistance with that. If you'd like letter briefing on it or if you'd like to look at the summary judgment paper. But I understand the other side's argument now to be the claims cover nothing after Judge Williams found what the claims cover. So I'll stop there.

THE COURT: And I understand and I want to let the parties know that we are working through these as fast as we can. I have read the argument that you're talking about. We want to get you a decision on that as soon as we can. I can tell you, and I'm comfortable telling you, that this summary judgment motion is likely to be granted, but we

11:35:56 1 do want to make sure that we've read all the parties'
11:35:59 2 arguments. And in particular, we want to go back and look
11:36:02 3 to see what exactly everyone argued to Judge Williams at the
11:36:07 4 claim construction.

11:36:07 5 But the summary judgment of infringement, my
11:36:11 6 inclination is that that will be granted, so I think we're
11:36:15 7 looking at the invalidity cases to be heard at the trial.

11:36:19 8 MR. MORIN: Thank you, Your Honor.

11:36:21 9 THE COURT: All right. Let's hear from
11:36:23 10 plaintiffs.

11:36:23 11 MS. LO: Sorry. Thank you. Apologies for
11:36:25 12 jumping the gun there. We understand that you were
11:36:28 13 referring to Sarepta's motion for summary judgment no. 1 on
11:36:32 14 infringement.

11:36:33 15 THE COURT: Yes.

11:36:34 16 MS. LO: And I thank you for letting us know.
11:36:36 17 Again, if you do decide that in favor of Sarepta, we will
11:36:41 18 stipulate to infringement obviously. And that relates to
11:36:44 19 one claim construction dispute.

11:36:46 20 There is another claim construction dispute
11:36:49 21 regarding the meaning of "antisense oligonucleotides" that
11:36:54 22 appears in the preamble of the Sarepta patent claims. This
11:36:58 23 has been briefed in connection with Nippon Shinyaku's
11:37:02 24 Daubert motion to exclude the testimony and opinions of Dr.
11:37:05 25 Daughgy, which is Sarepta's technical expert. I don't know

11:37:12 1 if you've read those papers or not, but again, this is, I
11:37:17 2 think this would be -- it would be helpful to have guidance
11:37:19 3 from the Court before trial, because it, you know, directly
11:37:22 4 effects the scope of witness testimony, et cetera. And we
11:37:27 5 do believe that it's a legal issue.

11:37:30 6 THE COURT: Thank you very much. I can tell you
11:37:32 7 that one we haven't looked at, but we will.

11:37:34 8 MS. LO: Thank you very much.

11:37:37 9 I also have a question relating to Nippon
11:37:43 10 Shinyaku's breach of contract claims. We have a pending
11:37:46 11 motion for summary judgment no. 3 on breach of contract, but
11:37:51 12 if you deny that, then we would request a bench trial on
11:37:55 13 that claim. And I'm not sure -- and so we wanted to raise
11:38:00 14 that to your attention since it might not necessarily be
11:38:04 15 clear just from a logistics standpoint and for your
11:38:08 16 consideration.

11:38:09 17 THE COURT: Okay. All right. What's the other
11:38:12 18 side's position on whether that's appropriate for a bench
11:38:15 19 trial?

11:38:15 20 MR. MORIN: We have no problem with that being a
11:38:17 21 bench issue. That is one that I think hopefully our friends
11:38:21 22 will agree need not be taken up next week. I think -- I
11:38:26 23 think that if we get the immediate issues resolved, we're
11:38:31 24 likely to be able to resolve that final issue without
11:38:34 25 burdening you with a bench trial on the issue. It has to do

11:38:37 1 with the Federal Circuit decision that's already been
11:38:40 2 decided on that issue relating to the IPRs, Your Honor. I
11:38:44 3 won't go into more detail other than we agree it's for the
4 bench and hopefully our friends agree it wouldn't be good
11:38:47 5 use of the Court's time at our May trial. It's likely to be
11:38:51 6 resolvable between the parties, I think.

11:38:54 7 THE COURT: Well, why don't you meet and confer
11:38:56 8 on that and if there is an agreement that -- sounds like --
11:39:01 9 I'm not sure if what you're saying is that the issue is
11:39:04 10 going to fall away legally depending on what happens at the
11:39:08 11 jury trial or just as a practical matter it's going to fall
11:39:11 12 away, but maybe you all can meet and confer.

11:39:15 13 MR. MORIN: As a little preview, Your Honor, I
11:39:18 14 think as a practical matter, it's likely to fall away. It's
11:39:21 15 very nominal. Relative to the overall case, it's very
11:39:24 16 nominal in terms of damages and the Federal Circuit has
11:39:27 17 already kind of addressed the liability aspect of it. So
11:39:30 18 we'll meet and confer with the other side, but I think, you
11:39:33 19 know, if the other side wants Your Honor to rule on the
11:39:36 20 summary judgment motion, we have no, obviously, problem with
11:39:39 21 that, but even if Your Honor were to deny the summary
11:39:43 22 judgment motion, we think that that is unlikely to require
11:39:47 23 the Court's time ultimately. It's not a difference of very
11:39:51 24 much money in the scheme of things and it's not all that
11:39:54 25 much money in the scheme of the overall issues here today.

11:39:57 1 I think the parties are likely to be able to resolve that
11:40:00 2 issue if the Court doesn't resolve it on summary judgment.

11:40:02 3 THE COURT: Okay. Understood. Anything else
11:40:05 4 anyone wants to raise while we're all here?

11:40:08 5 MR. MORIN: There's another one. Please. The
11:40:10 6 other side should go. Please.

11:40:14 7 MS. LO: Thank you. My last question would be
11:40:18 8 regarding the order of presentation of evidence at trial.
11:40:22 9 It's Nippon Shinyaku's position that we should go first on
11:40:27 10 our declaratory judgment claims of the invalidity and
11:40:31 11 infringement, damages, et cetera, of Sarepta's patents, and
11:40:36 12 then Sarepta can rebut and then present its affirmative
11:40:41 13 claims and then we rebut. We think that would be the most
14 efficient and orderly presentation of evidence and require
11:40:47 15 less witnesses shuffling up and down. So that's our
11:40:50 16 proposal.

11:40:51 17 THE COURT: Have you talked to the other side
11:40:53 18 about it yet?

11:40:56 19 MS. LO: I believe we may have discussed it.
11:40:59 20 Unfortunately, I was not privy to those discussions, but we
11:41:03 21 have discussed it and I think that we were unable to reach
11:41:07 22 agreement.

11:41:09 23 MR. MORIN: Your Honor, this is Mike Morin. Oh,
11:41:12 24 please.

11:41:12 25 THE COURT: On this one, I don't want to say

11:41:14 1 anything more about that today. Why don't you meet and
11:41:17 2 confer and that's the kind of thing I think can get sorted
11:41:21 3 out at the pretrial conference.

11:41:23 4 MS. LO: Thank you, Your Honor.

11:41:26 5 MR. MORIN: The other one that we'd like to --
11:41:28 6 obviously the parties have a lot of motions in front of Your
11:41:31 7 Honor, as you reminded us in your letter last week. One
11:41:35 8 that's particularly important to us is there's a motion on
11:41:40 9 their expert Dr. Wood. I don't know if Your Honor and your
11:41:43 10 staff has had a chance to look at that yet. That's someone
11:41:48 11 who consulted for us very, very closely for years and years
11:41:50 12 in multiple projects, including with the lawyers on this
11:41:55 13 case, and then showed up as the other sides' expert and we
11:41:58 14 feel pretty strongly about this one. Hopefully the papers
11:42:01 15 made that out. We don't need to argue it today, but I just
11:42:04 16 want to make the Court aware that this is one of particular
11:42:09 17 importance and significant and it's personal to Sarepta as
11:42:13 18 well, so we just want to make sure it was high on your
11:42:16 19 priority list, the Dr. Wood preclusion.

11:42:18 20 THE COURT: It absolutely is on our list and
11:42:21 21 it's high on our list.

11:42:23 22 MR. MORIN: Thank you, Your Honor.

11:42:28 23 THE COURT: All right. I'm not hearing anything
11:42:30 24 else. This was actually very helpful, because I think this
11:42:36 25 will inform our decision on how we're going to move

11:42:39 1 forward. So we'll get you an answer as soon as we can and
11:42:42 2 you can look forward to rulings trickling out hopefully over
11:42:47 3 those next couple weeks that will get us ready for the
11:42:50 4 pretrial conference. Take care, everybody.

11:42:53 5 MR. MORIN: Thank you, Your Honor.

11:42:55 6 MS. LO: Thank you very much.

11:42:57 7 THE COURT: Bye bye.

8 (Teleconference concluded at 11:42 a.m.)

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I hereby certify the foregoing is a true and
accurate transcript from my stenographic notes in the
proceedings.

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/s/ Stacy M. Ingram, RPR
Official Court Reporter
U.S. District Court

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